

REMARKS

A. Claim Rejections 35 U.S.C. § 112

The Examiner has rejected Claims 1-18 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner states the limitation “the plug member lumen” lacks sufficient antecedent basis. Applicants have amended independent claims 1 and 11 to correct this deficiency and requests that the Examiner withdraw the rejection.

B. Claim Rejections 35 U.S.C. § 103

1. Claims 1-10 are patentable over Freeman and Brucker

Next, the Examiner rejected Claims 1-10 under 35 USC §103(a) as being unpatentable over U. S. Patent No. 6,306,114 to Freeman et al. (“Freeman”) in view of U. S. Patent No. 6,296,657 to Brucker (“Brucker”). The Examiner contends that Freeman discloses a biocompatible plug body with a lumen, a sealing member disposed within the lumen. The Examiner asserts that Freeman’s valves, identified as elements 20a-e, constitute the “sealing member.” Furthermore, the Examiner concludes that Freeman’s valves are “expandable across the lumen when exposed to fluid for substantially sealing the lumen from fluid flow therethrough” and that the valves may be “annularly-shaped.” Applicants respectfully disagree with these conclusions for the following reasons.

Foremost, Applicants submit that the sealing members disclosed by Freeman do not seal the lumen from fluid flow therethrough. Rather, as indicated above, the structures disclosed by Freeman are valves that selectively permit fluid flow. Specifically, the valves disclosed by Freeman allow fluid flow in one direction, but prevent it in the other. As the Freeman specification states:

The valve prevents tear fluid from passing from the eye through the stepped throughbore and into the lacrimal duct. However, when pressure builds up within the lacrimal duct, e.g., because of sneezing, ear popping, etc., the valve opens, thereby permitting the pressure to equalize and preventing the plug from dislodging.

Accordingly, the function of allowing fluid flow in one direction is an important aspect of the Freeman device. The Freeman specification further describes the importance of this function in the discussion of prior art plugs:

In addition, with prior art canalicular plugs, completely occluding the lacrimal duct can provoke other detrimental effects. For example, when a patient has a plug implanted in his or her lacrimal duct, simple acts such as sneezing or nose blowing can cause a momentary pressure differential to occur about the plug. That is, referring to prior art FIG. 25, the lacrimal duct 916 on the body side of the plug (below body 914) is subject to increased pressure relative to the head side of the plug (above head 914). This pressure differential can result in the plug being forced up and inadvertently dislodged from the puncta. Other activities, such as eye rubbing and ear-popping (e.g., after scuba diving or flying) can similarly cause a pressure differential and result in inadvertent expulsion of the plug from the lacrimal duct.

Thus, Freeman discloses a sealing member that seals a lumen from fluid flow in one direction, but permits fluid flow in the other direction. Further, one of skill in the art would not be motivated to modify the Freeman device to achieve a seal in both directions as this would run counter to Freeman's explicit teachings.

In contrast, Applicants' invention provides a sealing member that obstructs flow in both directions. Applicants respectfully submit this is an inherent feature of the claim language, but to expedite prosecution, Applicants have amended independent claim 1 to specifically recite this feature and emphasize the distinction. As one of skill in the art will recognize, the sealing members disclosed by Applicants, being expandable across the lumen, seal the lumen from fluid flow in either direction.

The Examiner has cited Brucker for its teaching of bioabsorbable materials. However, Applicants submit that this disclosure has no bearing on the differences in function between the sealing member of Claims 1-10 and the valves disclosed by Freeman.

Further, with respect to claims 2 and 3, these claims specify that the sealing member expands when exposed to fluid to seal the lumen and that a preferred material is an expandable gel foam. The Examiner reasons that Brucker discloses an expandable gel foam and that it would be obvious to modify the Freeman device with this material. As described above, Applicants respectfully submit that a critical function of the Freeman device is that the valve must allow

fluid flow in one direction. The use of a material that expands when exposed to fluid would not provide this valve function, as fluid flow would be prevented in both directions. Accordingly, Applicants urge that there is no motivation to combine Freeman with Brucker as suggested.

Next, with regard to Claim 4, the Examiner states that the valves of Freeman, identified as elements 20a-e, correspond to the sealing member and that the valve “may be annularly shaped.” In the previous response, Applicants respectfully submitted that Freeman does not disclose an “annularly shaped” sealing member. As discussed, annular means ring-like or ring shaped and does not believe any of Freeman’s valves are “ring-like.” For example, the elements 20a-e cited by the Examiner are either flap type valves having a hinged member that is secured along an edge or slit type valves that comprise a thin membrane having one or more straight cuts. In addition to the flapper valve and slit valve, the only other specific valve disclosed by Freeman is a duckbill valve. Applicants contend that none of these constitute a disclosure of an annularly shaped sealing member.

For the above reasons, Applicants respectfully submit that Freeman and Brucker fail to disclose the aspects of the invention specified in claims 1-10, particularly with regard to a sealing member that substantially seals the lumen from fluid flow therethrough in both directions. Accordingly, Applicants request that the Examiner reconsider and withdraw § 103 rejection of claims 1-10 over Freeman.

2. Claims 11-18 are patentable over Freeman, Brucker and Hermann

Next, the Examiner rejected claims 11-18 under 35 USC §103(a) as being unpatentable over Freeman and Brucker as discussed above, further in view of U. S. Patent No. 5,871,474 to Hermann et al. (“Hermann”). The Examiner cites Hermann for its teaching of a tapered lumen and contends that it renders the use of a sealing member comprising a coil of material obvious.

As discussed above, Applicants submit that Freeman requires the use of a valve that permits fluid flow in one direction. In contrast, Applicants’ sealing member, by “substantially sealing the lumen from fluid flow therethrough” prevents flow in either direction. Again, to expedite prosecution, Applicants have amended claim 11 to emphasize this distinction. Since Freeman explicitly teaches away from the use of a valve that obstructs flow in either direction,

Applicants submit one of skill in the art would have no motivation to make such a modification to Freeman. Thus, regardless of the teachings of Brucker or Hermann, they cannot compensate for this deficiency of the primary reference.

Further, the Examiner cites Hermann for its teaching of a helical thread on the outside of the apparatus. The Examiner suggests that such screw threads “may take the form of a coil and increase the traction of the sealing member within the body to effectively keep it in place,” concluding that it would be obvious to modify Freeman on this basis. In the previous response, Applicants submitted that the screw threads noted by the Examiner are present on the outer surface of the structure that is analogous to the plug body, not the sealing member. Since the screw threads disclosed by Hermann are on a completely different structure, Applicants submit that this disclosure is irrelevant to the design of the sealing member. Indeed, Hermann discloses a sealing member that is formed from an inflatable cuff. As such, there is clearly no connection between the screw threads and the sealing member.

Moreover, Applicants’ disclosure of the use of a coil of material to form the sealing member depends upon the ability of the coil of material to compress as it moved down the tapered lumen of the plug body, as shown, for example, in Applicants’ Figs. 6b and 6d. This corresponds to the claim requirement that “the sealing member being movable into the tapered portion for substantially sealing the lumen from fluid flow therethrough.” In contrast, the screw threads provided on the outer surface of the Hermann apparatus have no similar function.

Accordingly, Applicants respectfully submit that the Examiner has failed to provide a motivation for one of skill in the art to adapt the screw threads of Hermann to the claimed sealing member.

For the above reasons, Applicants request that the Examiner reconsider and withdraw the § 103 rejection of Claims 11-18 over Freeman in view of Brucker and Hermann.

3. Claims 19-20, 22-25, 27-28, 32-35 and 37 are patentable over Freeman, Brucker and Atkinson

Next, the Examiner rejected Claims 19-20, 22-25, 27-28, 32-35 and 37 under 35 USC §103(a) as being unpatentable over Freeman and Brucker as discussed above in view of U. S.

Patent No. 6,645,225 to Atkinson (“Atkinson”). The Examiner supplements the teachings of Freeman and Brucker discussed above with Atkinson’s disclosure of an elongate member lumen in communication with the plug member lumen and a second elongate member comprising a location indicator.

Applicants submit that the combination proposed by the Examiner fails to suggest a sealing member that seals the lumen from fluid flow in either direction. Applicants have amended claim 19 to emphasize this feature, which Applicants submit is an inherent feature of the claims. As discussed above, Freeman requires the use of a valve that permits fluid flow in one direction. As such, the teachings of Brucker and Atkinson do not overcome this deficiency. Since there is no motivation to combine the references in order to achieve a sealing member that seals the lumen from fluid flow in both directions, Applicants respectfully request that the Examiner withdraw the § 103(a) rejection of claims 19-20, 22-25, 27-28, and 32-35.

4. Claims 26, 31 and 36 are patentable over Freeman, Brucker, Atkinson and Sepetka

The Examiner then rejected Claims 26, 31 and 36 under 35 USC §103(a) as being unpatentable over Freeman, Brucker and Atkinson as discussed above, further in view of U. S. Patent No. 5,814,062 to Sepetka et al. (“Sepetka”). The Examiner cites the Sepetka reference for its teaching of an activation element.

As with the above rejections, Applicants note that the primary references fail to suggest the use of sealing member that seals the lumen against fluid flow in both directions. For the reasons discussed above, Freeman specifically teaches away from such a feature, so Sepetka cannot overcome this deficiency. With respect to this rejection, the Examiner states that “Freeman et al. disclose the claimed device, including the elongate member moving the sealing member into a smaller diameter portion of the plug member (Figures 15-16).” Applicants respectfully disagree with this interpretation of the Freeman reference. The elongate member does not engage the sealing member, but rather the seat 116 of the lumen. As described, valve 110 is biased to the closed direction regardless of the use of elongate member 160, and opens

only when a pressure differential exists across the valve. Accordingly, Applicants submit that Freeman fails to disclose or suggest the elongate member moving the sealing member.

For these reasons, Applicants respectfully request that the Examiner withdraw the § 103(a) rejection of Claims 26, 31 and 36.

5. Claims 29 and 30 are patentable over Freeman, Brucker, Atkinson and Davis or Sommercorn

Finally, the Examiner rejected claims 29 and 30 under 35 USC §103(a) as being unpatentable over Freeman, Brucker and Atkinson as discussed above, further in view of U. S. Patent No. 6,143,004 to Davis (“Davis”) with respect to Claim 29, and further in view of U. S. Patent No. 6,494,848 to Sommercorn et al. (“Sommercorn”) with respect to Claim 30. The Examiner cites Davis for its teaching of a bleed back lumen and Sommercorn for an expandable member that provides tactile feedback for the location of the distal end of an elongate member.

As discussed above, Applicants submit that the primary references fail to suggest the use of sealing member that seals the lumen from fluid flow in either direction. The secondary references Davis and Sommercorn cannot compensate for this deficiency since their teachings do not include any structure that corresponds to the plug member. Further, Freeman specifically teaches away from the use of a valve that obstructs flow in both directions. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the § 103(a) rejection of Claims 29 and 30.

C. Conclusion

Applicants respectfully request that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned collect at (415) 705-6377 if there are any

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Patent

outstanding issues or questions which can be resolved to allow this application to be passed to issue.

Respectfully submitted,

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